NIH director unlikely to grant exemption from controls for DNA experiments

The director of the US National Institutes of Health, Dr Donald Fredrickson, seems unlikely to accept in full the recommendation of the Recombinant DNA Advisory Committee (RAC) that a large body of recombinant DNA experiments be exempted from the guidelines established by the NIH, following widespread criticism of the implications of such a move.

Sources within the NIH say that Dr Fredrickson will probably approve a significant reduction in the safety precautions needed to carry out most experiments using as host the disabled K-12 strain of the bacterium *Escherichia coli*; these are said to account for between 80 and 85% of all experiments using recombinant DNA techniques.

But whereas the RAC, in a split 10 to 4 vote, decided at its last meeting in September to recommend *exemption* for the guidelines for such experiments — with merely the ruling that they should be registered with local biohazard committees, and should preferably be carried out at the minimal P1 physical containment level — Dr Fredrickson is likely to insist that the P1 conditions be enforced. This will include strict adherence to technician training requirements, and a ban on practices such as mouth-pipetting.

The NIH has had a flood of comments since the proposal to exempt the experiments was first put forward by RAC members Dr Allen Campbell and Dr Wallace Rowe at the committee's meeting in May. Many scientists wrote supporting the proposal, including in particular a petition signed by 183 scientists attending the Gordon conferences on nucleic acids and on biological regulatory mechanisms.

Others, however, have expressed concern about the implications of such a drastic move. Professor Roy Curtiss, of the department of microbiology at the University of Alabama in Birmingham, wrote to Dr Fredrickson criticising the proposed exemptions as premature, given the uncertainties that still exist over the hazards of recombinant organisms. "I believe that the RAC's recommendation to you was based more on the politics of science than on its data", he wrote.

Fredrickson: reviewing the arguments

In addition, the Natural Resources Defense Council in New York has demanded that an environmental impact statement be carried out for the proposed safeguard reductions, arguing that "the proposed exemptions are of such breadth and importance as to require full compliance with the National Environmental Policy Act."

In view of the controversy surrounding the committee's recommendation and its implications, Dr Frederickson has been carrying out a detailed review both of the arguments used during the RAC meeting, and of the data used to support them.

The results of this review will not be known for several weeks. However it is thought that Dr Fredrickson is reluctant to face the criticism that total exemption would involve.

For example, two weeks ago the citizens of Amherst, which has introduced a local ordinance requiring recombinant DNA research at the University of Amherst to be conducted under the NIH guidelines, agreed to require adherence to the 1978 revision of the guidelines, rather than their stricter 1976 original version.

However according to Dr Bruce Levin, a research scientist at the university who has been closely involved in the local debates, there would probably be strong resistance from the local community if a large proportion of the experiments were to be exempt from regulation.

Dr Fredrickson, however, is said to be prepared to accept most of the arguments in favour of a substantial reduction in required containment levels for many experiments involving the K-12 strain; one of the few areas still to be resolved is whether local committees would be required to give prior approval to experiments using biologically active materials, such as active polypeptides or active proteins.

The NIH is paying particular attention in its review to uncertainties that have arisen as a result of various risk assessment experiments, such as those which indicate that bacteria into which plasmids have been introduced can survive considerably longer than expected in the human gut.

Meanwhile staff members for Senator Adlai Stevenson's science and technology subcommittee are preparing legislation that would require all non-federally supported research involving recombinant DNA techniques — in particular that carried out by private companies — to register their experiments with the NIH. At present companies can register; but the arrangement is voluntary. □